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PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

Assistant Commissioner for Patents United States Patent and Trademark

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Date of mailing (day/month/year) 06 March 2000 (06.03.00)	in its capacity as elected Office
International application No. PCT/US99/12909	Applicant's or agent's file reference 15280-356-1PC
International filing date (day/month/year) 08 June 1999 (08.06.99)	Priority date (day/month/year) 11 June 1998 (11.06.98)
Applicant	
PASTAN, Ira, H. et al	

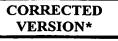
1.	The designated Office is hereby notified of its election made: X in the demand filed with the International Preliminary Examining Authority on:
	08 January 2000 (08.01.00)
	in a notice effecting later election filed with the International Bureau on:
2	The election V was
2.	The election X was was not
	made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).
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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

Nestor Santesso

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Telephone No.: (41-22) 338.83.38





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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 0:	ļ	(11) International Publication Number	r: WO 99/640/3
A61K 47/48	A3	(43) International Publication Date:	16 December 1999 (16.12.99)

PCT/US99/12909 (21) International Application Number:

8 June 1999 (08.06.99) (22) International Filing Date:

(30) Priority Data: 60/088,860 11 June 1998 (11.06.98) US

(71) Applicant (for all designated States except US): THE GOV-ERNMENT OF THE UNITED STATES, represented by THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUAN SERVICES [US/US]; Bethesda, MD 20892 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): PASTAN, Ira, H. [US/US]; 11710 Beall Mountain Road, Potomac, MD 20854 (US). BERA, Tapan, K. [US/US]; 18302 Uvy Oak Terrace, Gaithersberg, MD 20877 (US). KENNEDY, Paul, E. [US/US]; 735 Easly Street, Silver Spring, MD 20910 (US). BERGER, Edward, A. [US/US]; 5820 Inman Park Circle #230, Rockville, MD 20852 (US). BARBAS, Carlos, F., III [US/US]; 7081 Weller Street, San Diego, CA 92122 (US).

(74) Agents: STORELLA, John, R. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:

10 February 2000 (10.02.00)

(54) Title: RECOMBINANT IMMUNOTOXIN DIRECTED AGAINST THE HIV-1 GP120 ENVELOPE GLYCOPROTEIN

(57) Abstract

This invention provides an immunotoxin that specifically binds to and kills cells displaying an HIV gp120 coat protein. The immunotoxin comprises an anti-gp120 antibody directed to the conserved CD4 binding site of gp120 attached to a cytotoxin e.g. a Pseudomonas exotoxin. In one preferred embodiment the immunotoxin is a recombinantly expressed fusion protein comprising a single chain Fv region attached to a modified Pseudomonas exotoxin (3B3(Fv)-PE38).

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DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		
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Internation pplication No PCT/US 99/12909

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A. CLASSI IPC 6	FICATION OF SUBJECT MATTER A61K47/48			
According to	o International Patent Classification (IPC) or to both national classifica	tion and IPC		
B. FIELDS	SEARCHED			
Minimum do IPC 6	ocumentation searched (classification system followed by classification $A61K$	n symbols)		
Documental	tion searched other than minimum documentation to the extent that su	ich documents are inclu	uded in the fields searched	
Electronic d	ata base consulted during the international search (name of data bas	e and, where practical,	, search terms used)	
C. DOCUME	ENTS CONSIDERED TO BE RELEVANT			
Category ³	Citation of document, with indication, where appropriate, of the rele	vant passages	Relevant to claim No).
Х Р,Х	DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUM OHIO, US BERA, TAPAN K. ET AL: "Specific k HIV-infected lymphocytes by a rec immunotoxin directed against the envelope glycoprotein" retrieved from STN Database accession no. 129:229342 XP002125548 abstract & MOL. MED. (N. Y.) (1998), 4(6), , US 5 834 599 A (SUN BILL NAI-CHAU 10 November 1998 (1998-11-10) claims; examples	illing of ombinant HIV-1 384-391	1-56	
X Furti	her documents are listed in the continuation of box C.	X Patent family	members are listed in annex.	
"A" docume consid "E" earlier of filling d "L" docume which citation "O" docume other of the remember of the r	ent defining the general state of the art which is not dered to be of particular relevance document but published on or after the international date ent which may throw doubts on priority claim(s) or is cited to establish the publication date of another nor other special reason (as specified) ent referring to an oral disclosure, use, exhibition or means	or priority date and cited to understand invention "X" document of particular cannot be consided involve an invention "Y" document of particular cannot be consided document is combuments, such combuin the art.	dished after the international filing date d not in conflict with the application but d the principle or theory underlying the ular relevance; the claimed invention ared novel or cannot be considered to restep when the document is taken alone ular relevance; the claimed invention ared to involve an inventive step when the pined with one or more other such docupination being obvious to a person skilled of the same patent family	
Date of the	actual completion of the international search	Date of mailing of	the international search report	
1	4 December 1999	29/12/1	999	
Name and n	mailing address of the ISA European Patent Office. P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040. Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Berte,	М	



Internation pplication No PCT/US 99/12909

		PC1/US 99/12909
	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category ·	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US BERA, TAPAN K. ET AL: "A bivalent disulfide-stabilized Fv with improved antigen binding to erbB2" retrieved from STN Database accession no. 129:270188 XP002125549 abstract & J. MOL. BIOL. (1998), 281(3), 475-483,	1,6,12, 13,15, 25,28
Α	DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US PINCUS, SETH H. ET AL: "In vitro effects of anti-HIV immunotoxins directed against multiple epitopes on HIV type 1 envelope glycoprotein 160" retrieved from STN Database accession no. 125:185279 XP002125550 abstract & AIDS RES. HUM. RETROVIRUSES (1996), 12(11), 1041-1051,	1-56
Y .	LEE H. PAI ET AL.: "Anti-tumor activities of immunotoxins made of monoclonal antibody B3 and various forms of Pseudomonas exotoxin" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, vol. 88, April 1998 (1998-04), pages 3358-3362, XP002125579 WASHINGTON US cited in the application figure 3; table 1	1-56
X	DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US MATSUSHITA, SHUZO ET AL: "Selective killing of HIV-infected cells by anti-gp120 immunotoxins" retrieved from STN Database accession no. 112:151331 XP002125551 abstract & AIDS RES. HUM. RETROVIRUSES (1990), 6(2), 193-203,	1
Χ	US 5 458 878 A (CHAUDHARY VIJAY K ET AL) 17 October 1995 (1995-10-17)	1
Υ	cited in the application claims 1,2,7,9	1-56

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Internation: plication No
PCT/US 99/12909

		PC1/U3 99/	
C.(Continua	ation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category '	Citation of document, with indication, where appropriate, of the relevant passages	ļ	Relevant to claim No.
Y	WO 97 13529 A (US HEALTH ; KUAN CHIEN TSUN (US); PASTAN IRA (US)) 17 April 1997 (1997-04-17) claims 1,2,9,37		1-56
		;	
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Internacional application No.

PCT/US 99/12909

B x I Observations where certain claims w re found unsearchable (Continuation of item 1 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 33-51 because they relate to subject matter not required to be searched by this Authority. namely: Remark: Although claims 33-51 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.



Infon..ation on patent family members

Internation No
PCT/US 99/12909

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			EP	0861091 A	02-09-1998

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6:

A61K 47/48

A3

(11) International Publication Number: WO 99/64073

(43) International Publication Date: 16 December 1999 (16.12.99)

(21) International Application Number: PCT/US99/12909

(22) International Filing Date: 8 June 1999 (08.06.99)

60/088,860 11 June 1998 (11.06.98) US

(71) Applicant (for all designated States except US): THE GOVERNMENT OF THE UNITED STATES, represented by THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUAN SERVICES [US/US]; Bethesda, MD 20892 (US).

(72) Inventors; and

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(74) Agents: STORELLA, John, R. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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A. CLASSI IPC 6	FICATION OF SUBJECT MATTER A61K47/48					
According to	o International Patent Classification (IPC) or to both national classif	lication and IPC				
	SEARCHED					
Minimum do	ocumentation searched (classification system followed by classification $A61K$	ation symbols)				
Documenta	tion searched other than minimum documentation to the extent that	t such documents are include	ed in the fields se	earched		
Electronic d	ata base consulted during the international search (name of data b	pase and, where practical, so	earch terms used	i)		
	ENTS CONSIDERED TO BE RELEVANT					
Category 3	Citation of document, with indication, where appropriate, of the r	elevant passages		Relevant to claim No.		
x	DATABASE CHEMABS 'Online!			1-56		
	CHEMICAL ABSTRACTS SERVICE, COLU OHIO. US	JMBUS,				
	BERA, TAPAN K. ET AL: "Specific	killing of				
	HIV-infected lymphocytes by a re	ecombinant				
	immunotoxin directed against the envelope glycoprotein"	HIV-1				
	retrieved from STN	10				
	Database accession no. 129:22934 XP002125548	+2				
	abstract	204 201				
	& MOL. MED. (N. Y.) (1998), 4(6)), 384-391				
P,X	US 5 834 599 A (SUN BILL NAI-CHA	VII		1		
, , ^	10 November 1998 (1998-11-10)	AU EI AL)		1		
	claims; examples					
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X Furti	her documents are listed in the continuation of box C.	X Patent family me	embers are listed	in annex.		
° Special ca	tegories of cited documents :	"T" later document publish				
"A" docume consid	ent defining the general state of the art which is not lered to be of particular relevance	or priority date and n cited to understand the invention				
filing d		"X" document of particular cannot be considered	r relevance; the c	laimed invention be considered to		
which	nt which may throw doubts on priority claim(s) or is cited to establish the publication date of another n or other special reason (as specified)	"Y" document of particular	r relevance; the c			
	ent referring to an oral disclosure, use, exhibition or	document is combine	ed with one or mo	ventive step when the ore other such docu-		
"P" docume	other means ments, such combination being obvious to a person skilled in the art. "P" document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family					
<u> </u>	actual completion of the international search	Date of mailing of the				
1.	4 December 1999	29/12/199	99			
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	Tel. (+31-70) 340-2040. Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Berte, M				

Internation pplication No PCT/US 99/12909

C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category -	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US BERA, TAPAN K. ET AL: "A bivalent disulfide-stabilized Fv with improved antigen binding to erbB2" retrieved from STN Database accession no. 129:270188 XP002125549 abstract & J. MOL. BIOL. (1998), 281(3), 475-483,	1,6,12, 13,15, 25,28
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X	US 5 458 878 A (CHAUDHARY VIJAY K ET AL) 17 October 1995 (1995-10-17)	1
	cited in the application	



Internations plication No
PCT/US 99/12909

Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	PC1/U3 99/12909	
ategory '		Relevant to claim No.	
,	WO 97 13529 A (US HEALTH ;KUAN CHIEN TSUN (US); PASTAN IRA (US)) 17 April 1997 (1997-04-17) claims 1,2,9,37	1-56	

4

International application No.

PCT/US 99/12909

Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)			
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:				
1. X	Claims Nos.: 33-51 because they relate to subject matter not required to be searched by this Authority. namely: Remark: Although claims 33-51 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.			
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3.	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:			
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:			
Remari	The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.			

Information on patent family members

Internation: plication No PCT/US 99/12909

Patent document cited in search report	t	Publication date		atent family nember(s)	Publication date
" US 5834599	A	10-11-1998	AT	122237 T	15-05-1995
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Q V

TENT COOPERATION TREAT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference FOR FURTHER see Notification of Transmittal of International Search Repo (Form PCT/ISA/220) as well as, where applicable, item 5 be ACTION			
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)	
PCT/US 99/12909	08/06/1999	11/06/1998	
Applicant			
THE GOVERNMENT OF THE UNI	TED STATES as represented		
This International Search Report has bee according to Article 18. A copy is being to This International Search Report consists	-	nority and is transmitted to the applicant	
l 500	a copy of each prior art document cited in this	report.	
Basis of the report			
	international search was carried out on the ba ess otherwise indicated under this item.	sis of the international application in the	
the international search w Authority (Rule 23.1(b)).	as carried out on the basis of a translation of t	he international application furnished to this	
b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing: contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readble form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.			
	nd unsearchable (See Box I).		
3. Unity of invention is lac	King (see Box II).		
4. With regard to the title,			
the text is approved as su			
	shed by this Authority to read as follows: IN DIRECTED AGAINST THE HIV	-1 GP120 ENVELOPE GLYCOPROTEIN	
the text has been established	ubmitted by the applicant. Shed, according to Rule 38.2(b), by this Author e date of mailing of this international search re	ity as it appears in Box III. The applicant may, port, submit comments to this Authority.	
6. The figure of the drawings to be puber as suggested by the applicant fail because this figure bette	icant.	None of the figures.	



International application No.

PCT/US 99/12909

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 33-51 because they relate to subject matter not required to be searched by this Authority, namely: Remark: Although claims 33-51 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged
effects of the compound/composition. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

ternational Application No

A CLACE	IFICATION OF OUR IFOT MATTER				
A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61K47/48					
According to International Patent Classification (IPC) or to both national classification and IPC					
	SEARCHED				
	ocumentation searched (classification system followed by classificati	ion symbols)			
IPC 6	A61K	on oy25.2,			
Documenta	tion searched other than minimum documentation to the extent that s	such documents are included in the fields s	earched		
Electronic d	data base consulted during the international search (name of data ba	ise and, where practical, search terms used	d)		
C. DOCÚM	ENTS CONSIDERED TO BE RELEVANT				
Category °			1		
Category	Citation of document, with indication, where appropriate, of the rel	evant passages	Relevant to claim No.		
Х	DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUM	MBUS.	1-56		
	OHIO, US BERA, TAPAN K. ET AL: "Specific k	,			
	HIV-infected lymphocytes by a rec	combinant			
	immunotoxin directed against the				
	envelope glycoprotein"				
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P,X	US 5 834 599 A (SUN BILL NAI-CHAU	J ET AL)	1		
	10 November 1998 (1998-11-10) claims; examples				
·	Craims, examples				
	_	-/			
لنا	ner documents are listed in the continuation of box C.	χ Patent family members are listed	in annex.		
° Special car	tegories of cited documents :	"T" later document published after the inte			
	ent defining the general state of the art which is not lered to be of particular relevance	or priority date and not in conflict with cited to understand the principle or the invention			
"E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention					
"L" document which may throw doubts on priority claim(s) or involve an inventive step when the document is taken atone which is cited to establish the publication date of another					
"O" docume	"O" document referring to an oral disclosure, use, exhibition or document is combined with one or more other such docu-				
other means "P" document published prior to the international filing date but later than the priority date claimed "A document member of the same patent family "A document member of the same patent family					
Date of the a	actual completion of the international search	Date of mailing of the international sea			
14	4 December 1999	29/12/1999			
Name and m	nailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2	Authorized officer			
	NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,	Berte, M			
	Fax: (+31-70) 340-3016	Der ce, Pl	i		

ternational Application No

C (Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	Trc1/03 99/12909
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Y	LEE H. PAI ET AL.: "Anti-tumor activities of immunotoxins made of monoclonal antibody B3 and various forms of Pseudomonas exotoxin" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, vol. 88, April 1998 (1998-04), pages 3358-3362, XP002125579 WASHINGTON US cited in the application figure 3; table 1	1-56
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C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	<u> </u>	7/12909
Category °	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.
Y	WO 97 13529 A (US HEALTH ;KUAN CHIEN TSUN (US); PASTAN IRA (US)) 17 April 1997 (1997-04-17)		1-56
	1/ April 1997 (1997-04-17) claims 1,2,9,37		
			
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Creation date: 12-24-2003

Indexing Officer: TDANG5 - TIEN DANG

Team: OIPEBackFileIndexing

Dossier: 09673707

Legal Date: 11-08-2000

No.	Doccode	Number of pages
1	M905	1

Total number of pages: 1

Remarks:

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